STATUS OF CLAIMS

Claims 1, 3-4, 6-17 and 20 are now pending.

Independent Claims 1, 4, 13 and 20 have been amended.

Dependent Claims 2 and 5 have been cancelled without prejudice or disclaimer.

REMARKS

By this Amendment, Applicant has edited some of the Claims to further distinguish them over the prior art. Applicant has also explained why a Second Non-Final Office Action was improper, in which Patent Examiner John Alexander withdrew his earlier indications of allowance for original Claims 6-17 upon receiving an Amendment in which Applicant argued why the remaining, amended Claims should be allowed as well. Reconsideration and allowance of the application is respectfully requested.

In the First Office Action, Examiner Alexander: allowed original Claims 13-17; and, objected to original Dependent Claims 6-12 but indicated allowable subject matter. In addition, the Examiner rejected original Claims 18-19 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 4,985,014 to Orejola in view of U.S. Patent 5,439,448 to Leschinsky *et al.*; and, rejected around our original Claims 1-5, also under 35 U.S.C. § 103, using various combinations of U.S. Patent 5,360,395 to Utterberg, Leschinsky, and U.S. Patent 6,890,316 to Rawles *et al.*

In the First Office Action, Examiner Alexander stated the following reasons for indicating allowable subject matter:

> **Claim 6-12** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten and independent form including all of the limitations of the base claim and any intervening claims. The following is the statement of reasons for the indication of allowable subject matter: regarding Claims 6 and 7, the prior art of record does not disclose or suggest a system with the elements of Claim 4 and further including a peristaltic pump from a medical facility's cardiopulmonary bypass machine. Regarding Claims 8-12, the prior art of record does not disclose or suggest a system with the elements

of Claim 4 and further including a second sterile atrial-arterial shunt sealed in the container and generally identical to the first shunt. (Emphasis added by Applicant's undersigned attorney.)

Claims 13-17 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not disclose or suggest a method of pump-assisted myocardial revascularization without cardiopulmonary bypass that includes surgically attaching first and second cannulae to the aorta and left atrium respectively, interconnecting the first and second cannulae having vented cannula adapters, and inserting the tubing into a peristaltic pump from a medical facility's cardiopulmonary bypass machine. (Emphasis added by Applicant's undersigned attorney.)

Applicant subsequently amended rejected Independent Claims 1 and 4 and argued for their patentability in an Amendment[1] submitted March 6, 2006. In response, Examiner Alexander withdrew his indications of allowance as to Claims 6-17 in the Second Office Action. The Examiner instead improperly rejected Claims 6-17, as well as the remaining pending Claims. When the undersigned telephoned Examiner Alexander on May 15, 2006 for an explanation, he found that Examiner Alexander was no longer at the Patent Office.

There are multiple reasons why the Second Office Action is improper. For example:

1. There is no teaching in any of the cited patents to combine them in the new manners proposed by Examiner Alexander. The Examiner has improperly relied on knowledge derived solely from Applicant's own disclosure (i.e., application) as the basis to combine those references. That type of hindsight rejection is frowned upon by the Board of Appeals and the Federal Circuit.

2. Even if the proposed combination of patents was proper, Examiner Alexander admitted that those patents do not teach some claimed features. To overcome that, the Examiner basically stated, "it would seem" obvious

[1] Applicant also added a new Independent Claim 20 and cancelled some non-allowed Claims.

that someone skilled in this field could fill in the gaps. That is the epitome of hindsight rejections.

Specifically, Examiner Alexander rejected Claims 1, 2, 13, 14 and 20 under 35 U.S.C. § 103 as being unpatentable over a proposed combination of U.S. Pat. No. 4,662,355 to Pieronne *et al.* ("Pieronne") in view of U.S. Pat. No. 5,439,448 to Leschinsky *et al.* ("Leschinsky"). Pieronne was a newly cited reference. Leschinsky was previously cited in the First Office Action.

Examiner Alexander stated in his rejections of Claims 1, 13 and 20: "Here, examiner considers that Pieronne *et al.*' air purges (i.e. vents for priming purposes) inherently include a sealing means for opening and closing the vents.... [Also] Leschinsky *et al.* ... provide a teaching that blood-carrying tubing is most preferably formed of a clear material (Col. 6, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teaching by Leschinsky *et al.* to modify the tubing of Pieronne *et al.* to be translucent. The modification would have been to enable the clinician to view the interior of the tubing to detect bubbles...."

Further, Examiner Alexander stated: "Regarding Claim 2, as related above, it seems that the vents of Pieronne *et al.* inherently include a sealing means. However, Pieronne *et al.* do not explicitly disclose a cap removably attached to each vent. The system and method of Leschinsky *et al.* include removably attached caps for selectively opening and closing the vents during priming.... It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Leschinsky *et al.* to modify the priming vents of Pieronne *et al.* to include removably attached caps. The motivation would have been to provide an easy, well-known means for closing the vents during normal pumping and opening them during priming to allow air bubbles to escape to the exterior environment." (Emphasis added by Applicant's undersigned attorney.)

Applicant submits that Pieronne's "air purges" are unclear terms[2]; they are not necessarily "priming vents." The term "air purges" therefore does not teach or suggest the structure claimed. Where then did the Examiner derive the requisite motivation for combining the references... with their alleged inherent (but silent) features? Nowhere other than Applicant's own disclosure.

While unnecessary, Applicant has revised Independent Claims 1 and 4. Applicant has incorporated the subject matter of now-cancelled Dependent Claim 2 and 5, respectively, into those Claims. Applicant has chosen to do so to strengthen its patent (if allowed) in any infringement action. Claims 1 and 4 now specify that the sealing means comprises a cap removably attached to the vent of each cannula adapter for selectively opening and closing the vent for priming purposes. Applicant has also added language to explain that the priming is achieved by a patient's own blood flow.

Examiner Alexander had suggested that "a peristaltic pump *connected* to" be changed in 4.b.iii to read "a peristaltic pump *for connection* to" (emphasis added). Applicant prefers to continue to positively recite that "pump" feature. There is no limitation as to the pump's location, as alleged by the Examiner.

Claim 4 also states that there are two clamps removably attached to cannulae to block the patient's blood flow until priming as desired.

Where Pieronne *et al.* only mentions "air purges," Applicant submits that Pieronne does not teach or even suggest that the air purging can be done by a patient's own blood... much less that the purging is done with removable caps and translucent tubing to detect bubbles for extraction. Consequently, Claims 1 and 4 (especially with its removable clamps) are allowable over the prior art.

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[2] Applicant's undersigned attorney holds a B.S.E. degree in Aerodynamics and worked in fluidics as a Patent Examiner in Class 415, Rotary Pumps and Turbines. An "air purge" is an unclear term. It could be a check valve.

As mentioned above, Examiner Alexander rejected Independent Claims 13 and 20 (among others) as being unpatentable over a proposed combination of Pieronne and Leschinsky. While perhaps unnecessary, Applicant has revised Claims 13 and 20 to further distance itself from the applied references. Applicant has shifted some qualifying language from their original preambles into their bodies. The last steps in Claims 13 and 20 now recite: "whereby... [the aforementioned steps] perform pump-assisted myocardial revascularization without cardiopulmonary bypass." Note that neither Pieronne nor Leschinsky performs myocardial revascularization without cardiopulmonary bypass. Pieronne, the primary reference, deals with the regulation of **bypass** circuits (see, e.g., column 1, lines 6-7). Leschinsky is a "Bubble-Free Connector for Liquid Carrying Tubing." Consequently, Claims 14 and 20 (at least as amended) are allowable over the proposed combination... for this reason alone.

In the Second Office Action, Examiner Alexander also rejected Dependent Claims 3 and 15 under 35 U.S.C. § 103 as being unpatentable over a proposed combination of Pieronne, Leschinsky, and U.S. Pat. No. 6,935,344 to Aboul-Hosn *et al.* The Examiner stated, "Pieronne *et al.* do not explicitly disclose that the pump is placed within one meter of the patient or the tubing is no longer than two meters." Applicant stated in its Specification (¶ 34) that its novel apparatus would cut down the length of tubing currently used. This short length will save lives by reducing "the amount of blood required to fill the shunt for use in pump-assisted myocardial revascularization" (see original, pending Claims 3, 7, 12, 15, 17; and, see ¶ 6 of the Specification). It is disingenuous for the Examiner to fluff off the short length as being obvious over the prior art... without any clear teachings from the cited references. Applicant submits Dependent Claims 3 and 15 are allowable over the cited prior art.

The hindsight rejections continued. Examiner Alexander also rejected Claim 16 without finding Applicant's claimed fourth cannula attached to the right atrium. Nonetheless, the Examiner flew by that feature claiming that it was inherently taught by yet another reference, U.S. Pat. No. 5,743,045 to Runge. If the Office affirms that rejection, please explain the reasoning fully to clarify the issues for appeal.

Applicant submits that Examiner Alexander's prior indications of allowance should be reinstated for Method Claims 13-17: "the prior art of record does not disclose or suggest a method of pump-assisted myocardial revascularization without cardiopulmonary bypass that includes surgically attaching first and second cannulae to the aorta and left atrium respectively, interconnecting the first and second cannulae having vented cannula adapters, and inserting the tubing into a peristaltic pump from a medical facility's cardiopulmonary bypass machine."

Applicant has amended Independent Claim 20 beyond that mentioned above. This method Claim now also includes the following recitations: "priming the first shunt with the patient's own blood to remove air"; "limiting the length of the section of translucent tubing to no more than two meters to reduce the amount of the patient's blood required to fill the shunt for use in pump-assisted myocardial revascularization"; and "moving the peristaltic pump within one meter of the patient." Consequently, Claim 20 (at least as amended) is allowable for these recitations as well.

The remaining pending claims are Dependent Claims 6-12 and 14. Each is allowable, as it depends from clearly allowable Independent Claim 4 or 13 discussed above. Each is also self-explanatory, so no further detail is needed.

Applicant believes that its application is now in condition for allowance. Accordingly, Applicant requests that a Notice of Allowance be issued.

Respectfully submitted,

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[02082P13]